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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002953482 for a patent by DRUG DELIVERY SOLUTIONS PTY LTD as filed on 20 December 2002.

I further certify that the name of the applicant has been amended to ACRUX DDS PTY LTD pursuant to the provisions of Section 104 of the Patents Act 1990.

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Sixteenth day of January 2004

J. Billingsley

JULIE BILLINGSLEY
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AUSTRALIA
Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: DISPENSING DEVICE

Applicant: DRUG DELIVERY SOLUTIONS PTY. LTD.

The invention is described in the following statement:

DISPENSING DEVICE

This invention relates to a device for dispensing a substance, such as a pharmaceutical, medicinal, or therapeutic substance. The device is particularly, but not exclusively, suited for dispensing a substance in the form of a spray or mist. The invention will be hereinafter described with particular reference to transdermal and/or percutaneous delivery of substances, but it is to be understood that the invention has broader application.

It is usually the case that devices of the foregoing kind can be used on several occasions before the quantity of the substance stored in the device is exhausted. It is also a common requirement that an accurately metered amount of the substance is dispensed each time the device is operated.

Substance dispensing devices of the foregoing kind tend to suffer an unacceptable loss of the substance in the period between uses of the device. That loss is particularly evident in circumstances involving use of a volatile substance. Unintentional loss of the substance is wasteful, and can also interfere with the ability of the device to dispense an accurately metered quantity each time the device is operated. In that regard, accurate metering can be very important in some circumstances.

It is also desirable to guard against possible contamination of the substance by dust and/or other foreign material collecting at or adjacent the substance outlet of the device. That problem is sometimes attended to by providing the device with a removable dust cap which must be replaced after each use of the device. A disadvantage of that solution is that users can overlook the need to replace the cap, and may deliberately refrain from replacing the cap because of the inconvenience involved.

Still another difficulty encountered with conventional devices is the lack of protection against inadvertent or unintentional operation of the device. In the absence of such protection it may be possible for a child to operate the device, and in some circumstances that could have severe adverse consequences.

Yet another problem arises because many devices of the foregoing kind are bulky and/or uncomfortable to use. Bulky devices are difficult to carry, and may be left behind for that reason. Devices that are uncomfortable to use may be neglected because of that fact. In either case – ie., bulky or difficult to use – there is a risk of the user not using the device according to a prescribed

program, and as a consequence not obtaining the full benefit of the substance contained in the device.

It is an object of the present invention to provide a substance dispensing device having means for preventing, or minimising, unintentional loss of the substance. It is a further object of the invention to provide a substance dispensing device having convenient and effective means for preventing, or minimising, collection of dust or other foreign material at or adjacent the substance outlet of the device. Still another object of the invention is to provide a substance dispensing device having means for preventing, or minimising, inadvertent or unintentional operation of the device. Yet another object of the invention is to provide a substance dispensing device that is of relatively compact and convenient to use form.

According to one aspect of the present invention, there is provided a substance dispensing device having means for closing the outlet of the device when the device is not in use. The outlet closing means can be of any suitable form. In a preferred form however, that means includes a closure member that is adapted to engage within or against the device outlet so as to thereby close the outlet. In a further preferred form, the closure member is associated with a movable part of the device that is moved from a rest position to a use position in order to condition the device for operative use. The arrangement may be such that the closure member responds to movement of the movable part so as to engage within or against the outlet when the movable part is in the rest position, and to be located clear of the outlet when the movable part is in the use condition.

The aforementioned movable part may form at least part of means for guarding against collection of dust or other foreign material at or adjacent the device outlet.

According to a second aspect of the present invention, there is provided a substance dispensing device having a cover member that is moved from a rest position to a use position in order to condition the device for operative use. The arrangement is such that the cover member overlies and protects the device outlet when that member is in the rest position, and exposes the outlet to permit the substance to be expelled when in the use position. In one preferred arrangement, the cover member is formed of two relatively movable parts that

are moved together to adopt the rest position, and are moved apart to adopt the use position. Those parts may function as a partial shroud that confines the spread of the substance as it is emitted from the device outlet. The two movable parts may also function as a reference means for selecting an appropriate distance between the device outlet and the substance target area when the device is in use.

According to a third aspect of the present invention, there is provided a substance dispensing device having locking means that is operative to prevent operation of the device, and release means that is operable to render the locking means inoperative. It is preferred that the device also includes a movable part that is moved from a rest position to a use position in order to condition the device for operative use. The locking means may be responsive to movement of that part from the use position to the rest position so as to automatically return to the operative condition as the movable part moves towards or into the rest position. The movable part may form a cover member as described above, or it may form part of such a member.

According to a fourth aspect of the present invention, there is provided a substance dispensing device having a body, and a chamber within the body for receiving a substance capsule, wherein the body includes two relatively movable parts that are moved apart to condition the device for operative use, and are moved together to reduce the overall size of the device when the device is not in use. The two movable parts may cooperate to form a cover member as described above.

It will be convenient to hereinafter describe the invention in greater detail by reference to the accompanying drawings showing a dispensing device to which the invention, according to any one of its aspects, can be applied. The particularity of those drawings and the related description is not to be understood as superseding the generality of the preceding description of the invention according to each of its aspects. The drawings show an example embodiment of each aspect of the invention previously identified.

Figures 1 to 4 show an example device 1 to which an embodiment of each aspect of the invention has been applied. The device 1 includes a hollow body 2 that defines a chamber 3 (Figure 3) for receiving a substance capsule 4. The contents (the substance) of the capsule 4 will be selected to suit the

intended use of the device 1. In the example shown, the capsule 4 includes a manually operable pump 5 for dispensing a metered quantity of the substance. Other arrangements could be adopted, such as an aerosol-type dispenser.

In the arrangement shown, the body 2 includes two parts 6 and 7 that are movable relative to one another about the central axis 8 (Figure 3) of the chamber 3 for a reason hereinafter explained. The body parts 6 and 7 may be connected together in any appropriate manner. By way of example, the two parts 6 and 7 may snap engage with one another. If desired, the connection between the two parts 6 and 7 may be releasable to enable removal and possible replacement of the capsule 4. In some circumstances however, such replacement may not be permitted because of health regulations.

Figure 5 is an exploded view of the two body parts 6 and 7 showing one form of connecting means enabling snap connection of those parts. In the example shown, the connecting means includes at least one detent rib 9 provided on the outside of the body part 6, and a cooperable ledge 10 provided on the inside of the body part 7. It is preferred to provide two ribs 9 arranged in diametrically opposed relationship on the body part 6, and to provide two ledges 10 at appropriate positions on the body part 7. As shown, the detent ribs 9 may be provided on a cylindrical neck portion 11 of the body part that is of reduced diameter so as to fit within the lower open end 12 of the body part 7. Each detent rib 9 has a sloping upper surface 13 to facilitate movement across the respective cooperative ledge 10, and an abrupt lower surface 14 that locates over the ledge 10 so as to resist separation of the two parts 6 and 7. The lower edge 15 of the body part 7 may slidably engage a shoulder 16 of the body part 6 when the two parts 6 and 7 are connected together.

It is preferred to provide means for limiting the degree to which the two parts 6 and 7 can rotate relative to one another about the axis 8. In the particular arrangement shown by Figure 5, that limiting means includes a stop 17 located at each end of each of the ledges 10. The distance between the stops 17 of a ledge 10 is related to the length of the rib 9 engaging that ledge 10 so that the body parts 6 and 7 are capable of an appropriate degree of relative movement.

The body part 6 may be provided with capsule retaining means that is operative to prevent or resist relative rotation of the capsule 4 about the axis 8.

As shown, the capsule retaining means may include a plurality of ribs 18 provided on the inside surface of the chamber 3 and arranged to grip the capsule 4 to an extent sufficient to resist relative rotation of the capsule 4.

Also in the arrangement shown, an actuator button 19 is accessible at an upper end of the body 2 and cooperates with the pump 5 in a manner such that depression of the button 19 causes operation of the pump 5. When the pump 5 is operated, the substance is expelled through an outlet nozzle 20 of the pump 5, possibly in the form of a spray. The pump 5 operates in a known manner to pressurize the contents of the capsule 4 and thereby force a metered quantity of the substance to be expelled through the nozzle 20. At least one longitudinally extending rib 21 may be provided on the button 19 so as to resist separation of the button 19 from body 2. As shown by Figure 3, the upper end of the rib 21 is engageable with an opposed surface 22 of the body part 7. Other forms of button retaining means could be used.

The body parts 6 and 7 are relatively movable between a rest position as shown by Figures 1 and 2, and a use position as shown by Figure 4. When the parts 6 and 7 are in the rest position, it is preferred that stop means (as hereinafter described) is operative to prevent depression of the button 19 and thereby prevent operation of the pump 5. Also in that position, the parts 6 and 7 may cooperate to form a cover over the nozzle 20 and thereby inhibit collection of dust or other foreign material at or adjacent the nozzle 20. When the parts 6 and 7 are in the use position, the stop means is preferably deactivated, thereby allowing the button 19 to be depressed. Also in that position, the parts 6 and 7 are separated so as to expose the nozzle 20 and thereby provide a clear space through which the substance expelled through the nozzle 20 can move towards a target area.

It is a feature of a preferred embodiment of the invention that nozzle closing means is associated with one of the body parts 6 and 7 so as to be operative to close the nozzle 20 when the parts 6 and 7 are in the rest position. Closure of the nozzle 20 when the device 1 is not in use has the benefit of preventing or minimising unintentional loss of the substance. In the example shown, the nozzle closing means is formed by a member 23 attached to or formed integral with the body part 7. As shown by Figure 3, when the parts 6 and 7 are in the rest position, a terminal end of the member 23 bears against a

surface surrounding the nozzle 20 and thereby closes the nozzle 20. The member 23 is moved clear of the nozzle 20 when the parts 6 and 7 are moved to the use position (Figure 4).

The member 23 may also function as the stop means preventing operation of the actuator button 19 when the body parts 6 and 7 are in the rest position. For that purpose, the member 23 may project through an opening 24 in one side of the button 19. As will be apparent from Figure 3, when the parts 6 and 7 are in the rest position, the button 19 cannot be depressed to operate the pump 5 because of engagement between the member 23 and the upper edge 25 of the button opening 24. The button stop means is preferably disabled as a consequence of moving the body parts 6 and 7 into the use position as shown by Figure 4. That may be achieved in any appropriate manner. One satisfactory arrangement is shown by Figure 6, which is an exploded view of the actuator button 19 and the body part 7. In that particular arrangement, the member 23 is moved clear of the edge 25 when the body parts 6 and 7 are in the use position, and is aligned with an upward extension 26 of the opening 24. Downward movement of the button 19 is permitted as a consequence of the member 23 being receivable in the extension 26.

Releasable locking means may be provided to prevent the body parts 6 and 7 moving out of the rest position. In the particular arrangement shown, that locking means includes a detent 27 attached to or formed integral with the part 6, and an opening 28 formed in the part 7 and arranged to receive the detent 27 as shown by Figures 1 and 3. Other forms of locking means could be employed.

The locking means may be released in any suitable fashion. In the particular arrangement shown, the detent 27 is exposed at the outside of the body 2 and is therefore able to be employed as part of the release means. For that purpose, the detent 27 is provided at an end portion of a flexible arm 29 (Figure 3) attached to or formed integral with the body part 6. The arrangement is such that the detent 27 can be manually engaged and pressed into the chamber 3 so as to clear the opening 28 and thereby permit the parts 6 and 7 to be rotated about the axis 8 relative to one another.

In an alternative arrangement (not shown), a thin and flexible membrane may be attached to the part 7 so as to extend across the opening 28 and overly

the outer surface of the detent 27. The membrane thereby prevents direct contact with the detent 27, and may be opaque so as to hide the existence of the detent 27. In the latter case the membrane, or the body part 7, may be marked to indicate the need to press against the membrane in order to release the detent 27. In operation, the membrane is pressed so as to be deflected inwards to engage against the detent 27. Continued pressure against the membrane causes further deflection and results in release of the detent 27 as described above. One advantage of that arrangement is that it minimises the possibility of unintentional, or improper, use of the device 1. By way of example, the presence of the membrane can reduce the possibility of the device 1 being operated by a child.

Although the membrane is described above as being a separately formed member, it could be an integral part of the body part 7 as shown diagrammatically by Figure 3A. That is, the detent 27 may be received in an internal blind cavity 28, the base 28a of which is sufficiently flexible to function in the manner of the membrane described above.

The arm 29 preferably has sufficient resilience to move the detent 27 outwards when manually applied pressure is removed from the detent 27. As a result, the detent 27 is automatically returned to engagement within the opening 28 when the parts 6 and 7 are moved back into the rest position.

Effective operation of the release means by a child is made difficult by the fact that manual pressure must be retained on the detent 27 while the parts 6 and 7 are being moved out of the rest position. Premature release of pressure on the detent 27 will result in the detent 27 moving back into the opening 28 thereby preventing the parts 6 and 7 being moved to an extent sufficient to free the button 19 from the restraint of the stop means 23.

It is preferred that an outwardly extending wing section 30 is connected to or formed integral with the body part 6, and that a similar wing section 31 is connected to or formed integral with the body part 7. The wing sections 30 and 31 may cooperate to form cover means such as to prevent or minimise the collection of dust, or other foreign material, at or adjacent the nozzle 20. The wing sections 30 and 31 may include finger engageable portions 32 and 33 through which the user may apply pressure to cause separation of the wing

section 30 and 31, and thereby cause movement of the body parts 6 and 7 from the rest position to the use position.

When the wing sections 30 and 31 are separated to the full extent possible, they preferably form a partial shroud that confines the lateral spread of the substance expelled through the nozzle 20. At that separated condition, the wing sections 30 and 31 may also provide a reference for establishing a suitable distance between the nozzle 20 and the target area onto which substance expelled through the nozzle 20 is to be deposited.

It is preferred that a shallow cavity or recess 34 is provided in the outside surface of each of the wing sections 30 and 31. The arrangement of the recesses 34 is such that they provide convenient holding locations for the user when the wing sections 30 and 31 are separated as shown by Figure 4. That is, a user can comfortably grasp the device 1 in one hand by placing the thumb in one recess 34, and by placing one or two fingers in the other recess 34. The index finger can then be used to press the button 19 downwards and thereby operate the pump 5.

Appropriate positioning of the recesses 34 can enable the user to hold the device 1 by a squeeze action without causing the wing sections 30 and 31 to move inwards towards one another. That is, the squeeze action is applied in a line passing through, or close to, the axis 8. In addition, or alternatively, unintentional inward movement of the wing sections 30 and 31 may be resisted by suitable releasable holding means provided on the body parts 6 and 7. In one preferred arrangement, the holding means includes the detent 27 and a blind cavity 35 (Figure 5) formed in an inner surface of the body part 7. The cavity 35 is positioned to receive the detent 27, or part of that detent, when the body parts 6 and 7 are moved into the use position. The shape and/or depth of the cavity 35 is preferably such that the detent 27 can be forced out of the cavity 35 by moderate closing pressure applied to the wing sections 30 and 31. That is to be contrasted with the more positive locking action produced by location of the detent 27 within the opening 28, and which cannot be comfortably released without pressing the detent 27 inwards as previously described.

If desired, a viewing window 36 (Figure 3) may be provided in a side of the body part 6 to enable the user to see when the quantity of the substance in the capsule 4 is getting low. In that regard, the remaining quantity of the stored

substance may be observable because of the transparent nature of the container 36 (Figure 3) but forms part of the capsule 4. Alternatively, the remaining quantity may be indicated by a use indicator 37 (Figure 3) located within the body part 6. One form of such a use indicator as described in our co-pending patent application entitled "Usage Indicator" (reference IRN 629199).

It will be apparent from the foregoing description that a substance dispensing device incorporating the invention has an effective and easy to use closure means for preventing unintentional loss of the substance. The invention also provides for an effective and easy to use cover that prevents or inhibits collection of dust or other foreign material at or adjacent the device outlet. In addition, a device incorporating the invention is not easily operated by a child, and therefore has a desirable factor of safety. Furthermore, the device is of compact form, and is comfortable to use.

Finally, it is to be understood that various alterations, modifications and/or additions may be introduced into the constructions and arrangements of parts previously described without departing from the spirit or ambit of the invention.

DATED: 20 December 2002
PHILLIPS ORMONDE & FITZPATRICK
Attorneys for:
DRUG DELIVERY SOLUTIONS PTY LTD

David B Fitzpatrick

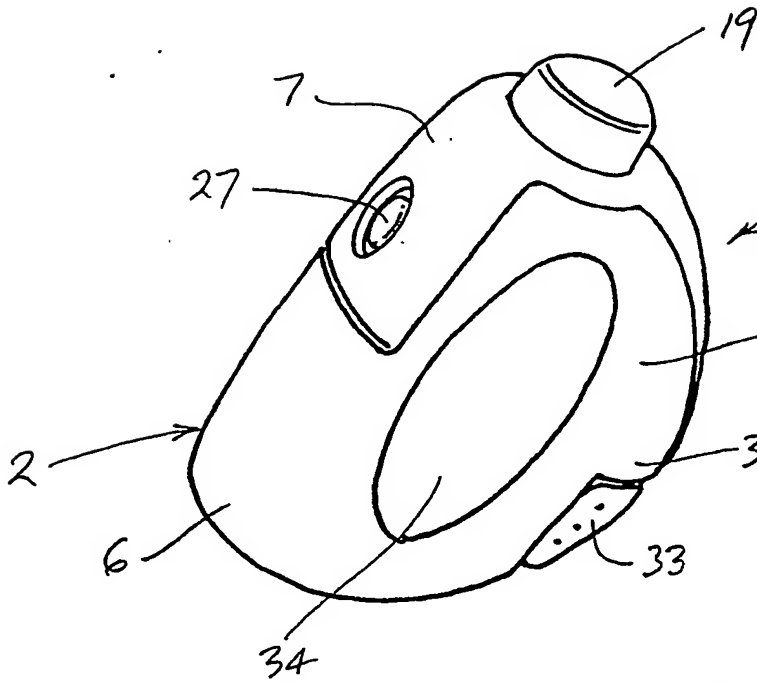


FIG. 1.

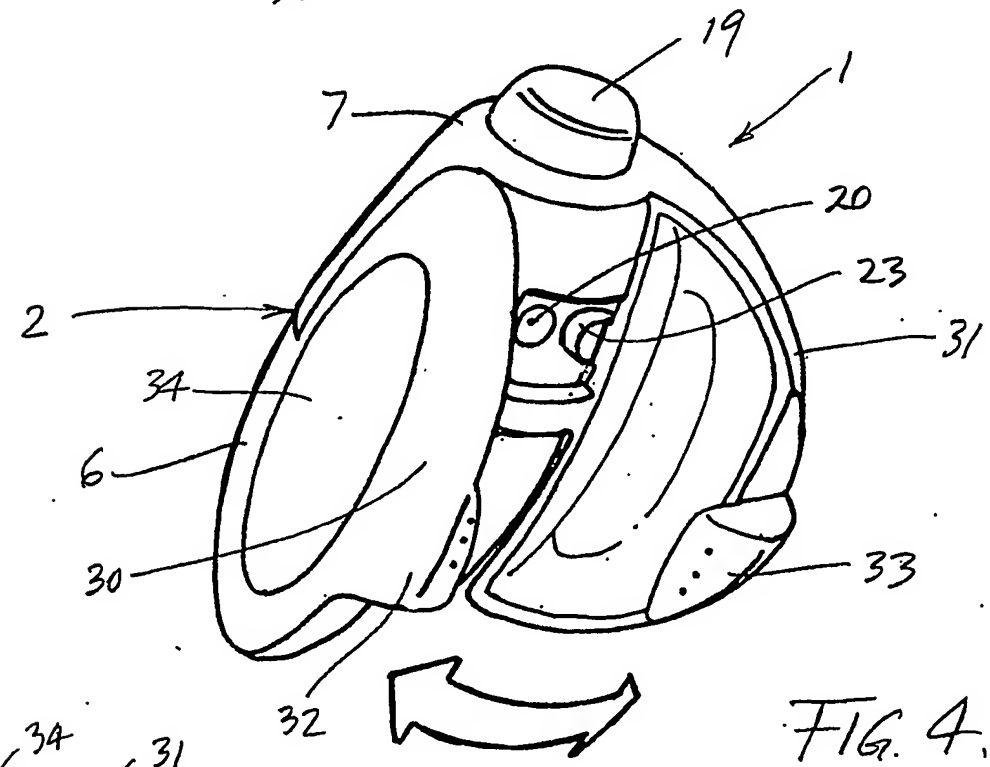


FIG. 4.

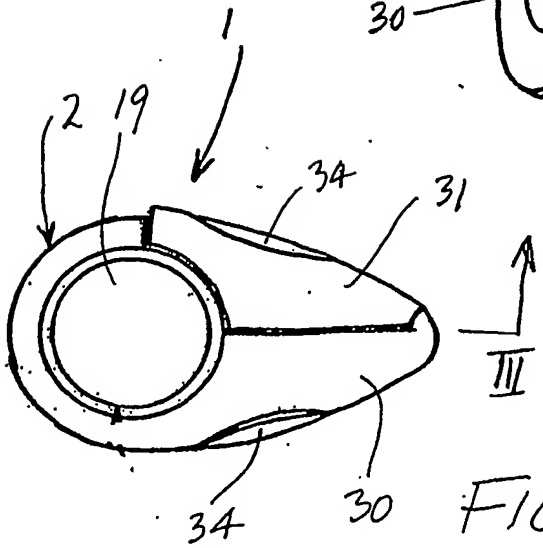
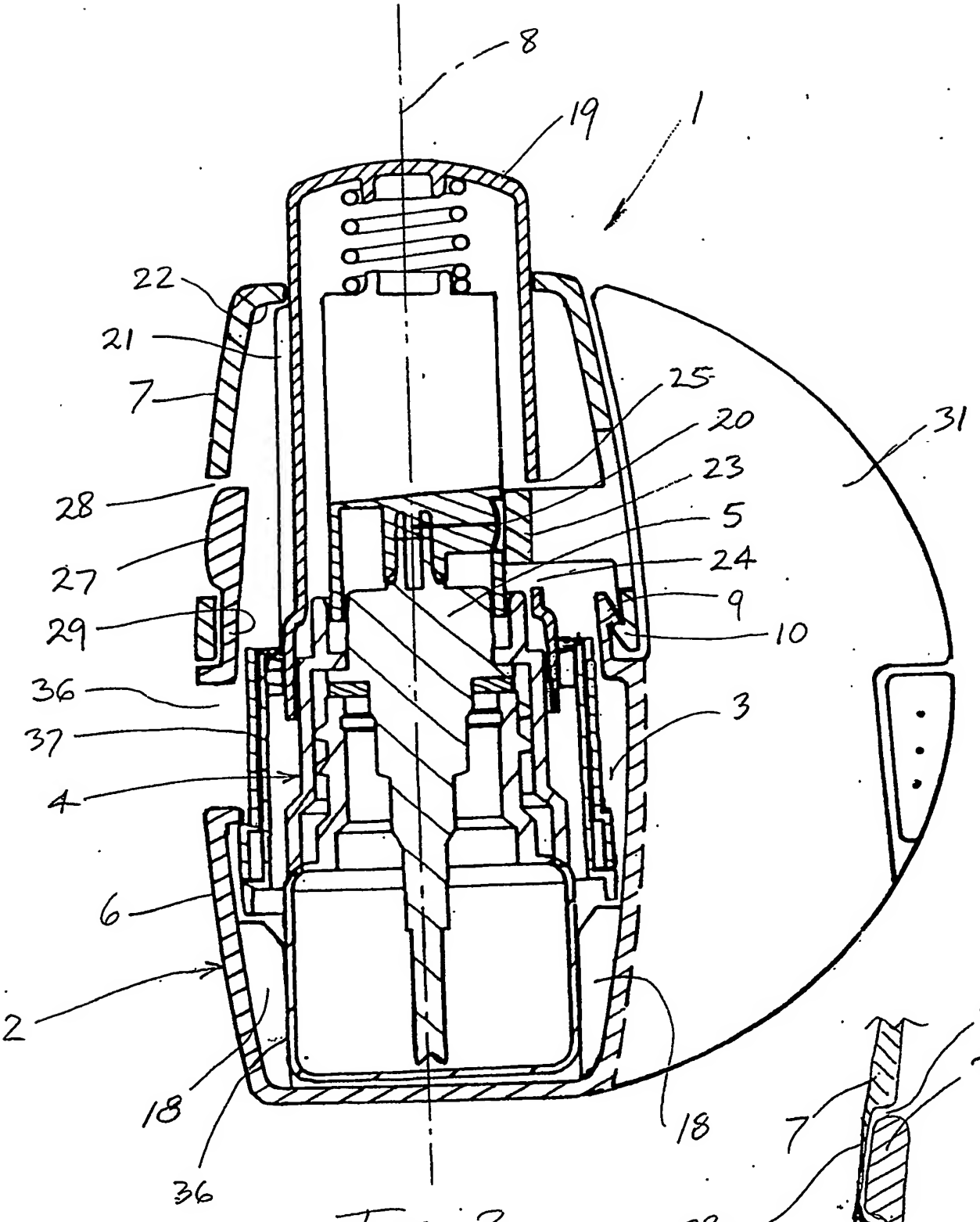


FIG. 2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28a

FIG. 3.

FIG. 3A.

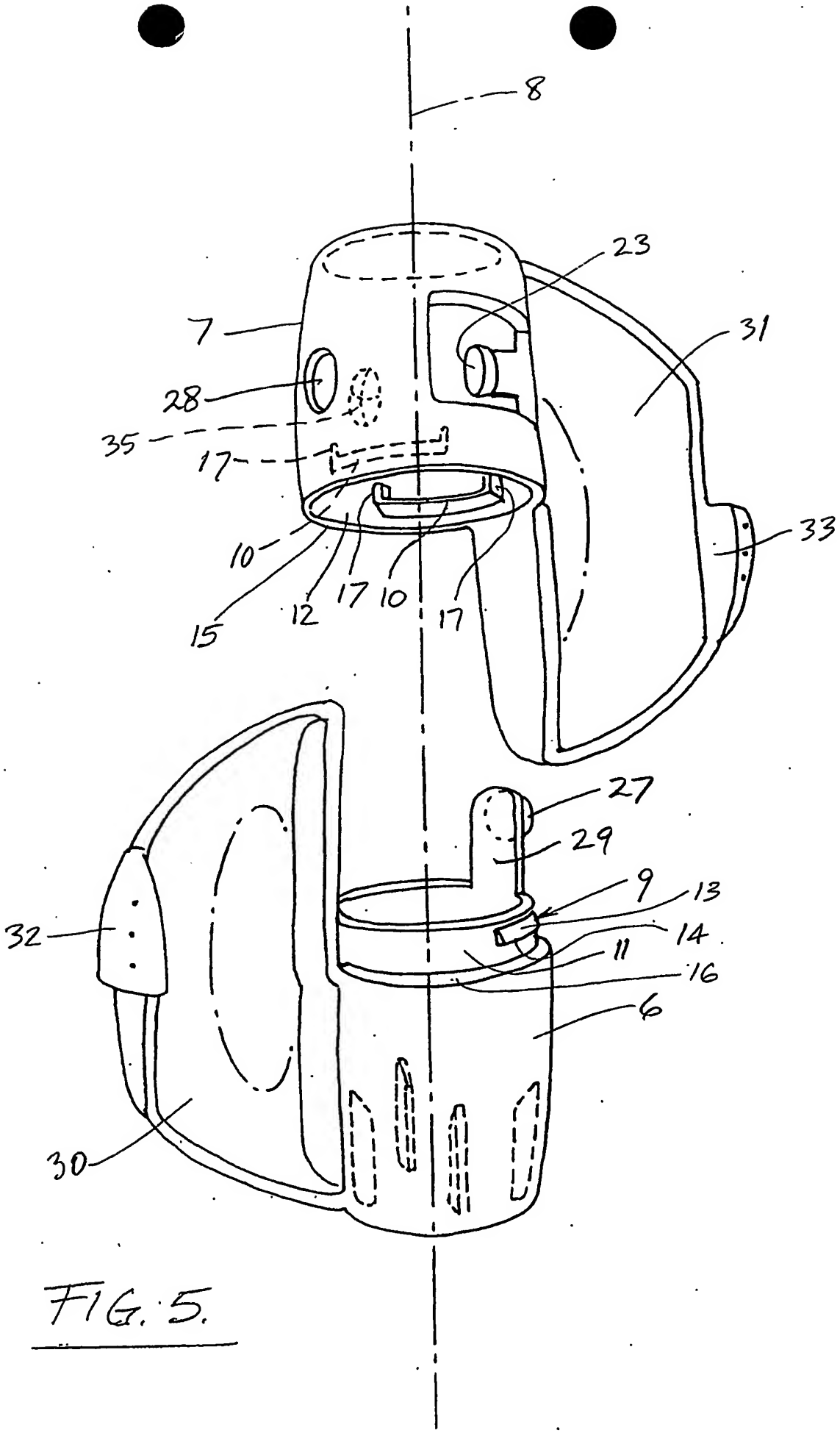

FIG. 5.

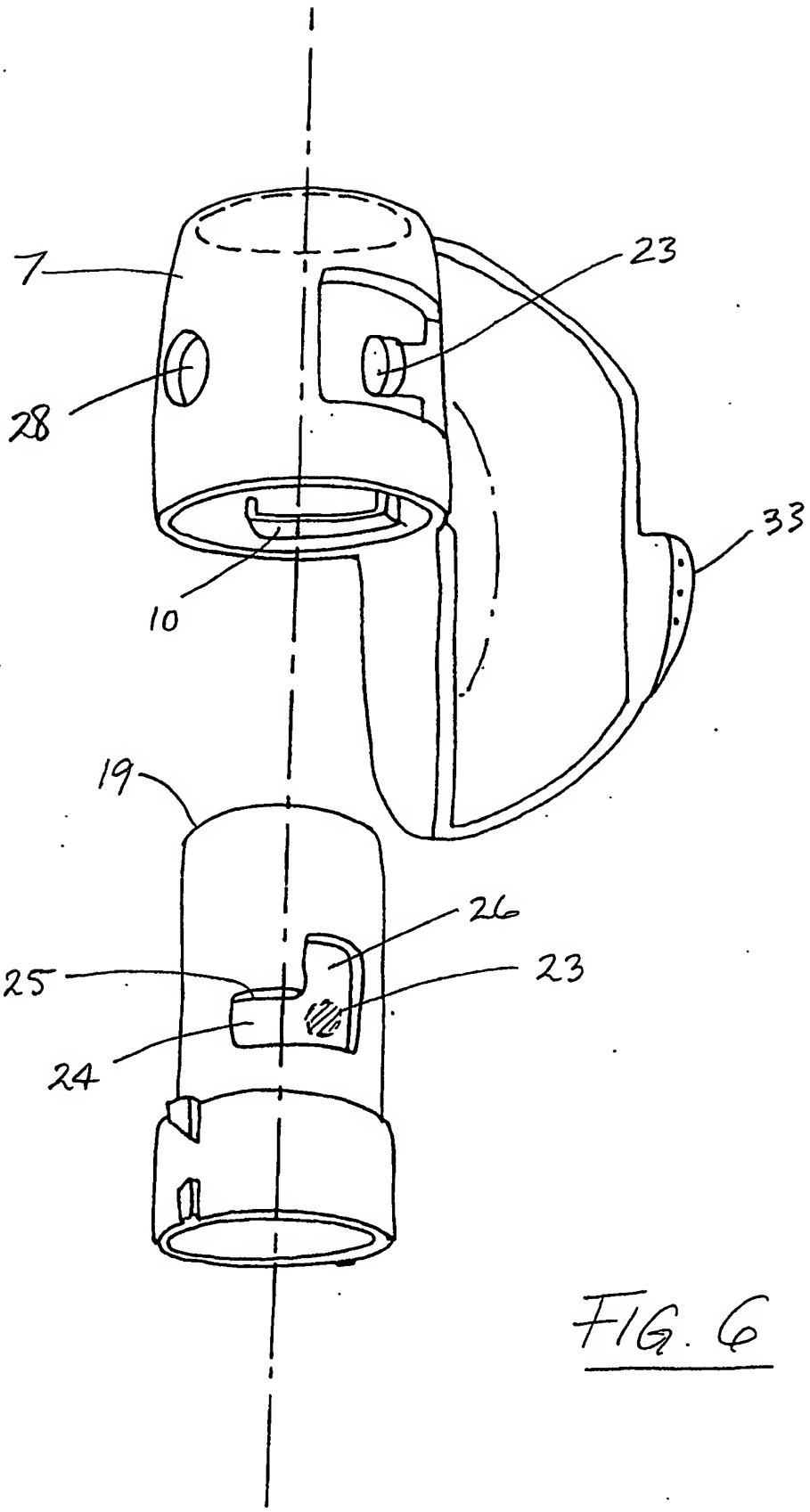

FIG. 6